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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,703	11/09/2001	Anne De Groot	17999-004 CON (BURF-4 CON	9101
7590	03/18/2004		EXAMINER	
MINTZ LEVIN One Financial Center Boston, MA 02111			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,703

Applicant(s)

GROOT, ANNE DE

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>011302</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's Response to Restriction, received 28 January 2004, is acknowledged.  
Applicant elects, without traverse, Invention II, claims 9-12, drawn to method of immunization, classified in class 424, subclass 9.1.
2. Claims 1-12 are pending. Claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Claims 9-12 are under consideration.

### **Priority Statement**

4. The status of the U.S. Patent Application 09/813,333 must be updated.

### **Specification**

5. The disclosure is objected to because of the following informalities:  
  
Page 5, line 18, should "as" be "has"?  
  
Page 5, line 19, what is meant by the phrase in the parentheses?  
  
Page 6, line 7, "a known peptides" should be "known peptides"  
  
Page 23, line 3, "paptides" should be "peptides"

Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1645

Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method for inducing anti-Mtb immune responses comprising administering to a mammal  $\geq 1$  peptide selected from the group consisting of SEQ ID NO:47, 49, 52, 61, 69, 72, 78, and 80, wherein administration is oral, topical, parenteral, intravascular or by viral infection.

The examples of the instant specification deal exclusive with epitope structure prediction, and *in vitro* proliferation assays using human subjects. The specification does not provide any data that any of the peptides were actually administered *in vivo* or that there is any *in vivo* induction of anti-Mtb responses. Therefore, the specification does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., *in vivo* induction of anti-Mtb responses using the claimed peptides.

### **Claim Rejections - 35 USC § 102**

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

Art Unit: 1645

application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Gennaro et al (U.S. Pat. No. 6,087,163).

The instant claims are drawn to a method for inducing anti-Mtb immune responses comprising administering to a mammal  $\geq 1$  peptide selected from the group consisting of SEQ ID NO:47, 49, 52, 61, 69, 72, 78, and 80, wherein administration is oral, topical, parenteral, intravascular or by viral infection.

As discussed above, the instant specification provides no examples of the claimed invention, only discussion of proposed use as claimed.

Gennaro et al teach an *M. tuberculosis* protein, SEQ ID NO:2, which comprises instant SEQ ID NO:69 peptide (col. 17, residues 56-75). Gennaro et al also teach that the invention includes the use of the claimed mature proteins or fragments thereof in tests (col. 3, lines 25-36). Gennaro et al also teach that the recombinant MPT63 protein as well as polypeptide portions thereof can be useful as components of a protein-based or subunit vaccine (col. 9, lines 6-11).

As with the instant specification, Gennaro et al does not provide actual examples of administering such peptides for inducing anti-Mtb immune responses. However, as with the instant specification, the teachings of Gennaro et al also speculate on the *in vivo* methods utilizing the peptide claimed.

### Conclusion

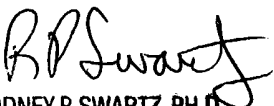
10. No claims are allowed.

Art Unit: 1645

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

March 16, 2004